Stephen Matlin â?? CEO, Life Length, Spain

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Stephen Matlin, CEO of Life Length, highlights the evolution of the company over recent years, especially the establishment of their own laboratories which have allowed them to conduct clinical studies for diagnostic and prognostic tests in cancer. Furthermore, he points out the need to better value preventative medicine and how they believe their tests can benefit the payer in the long-run.

How has the company evolved over the last 4 years?

In 2014, we were very much in the early stages of establishing the business. At that point, we were setting up our own laboratories, as originally, we were a spin-off of the CNIO. We realized that is we were going to make any headway along the long road ahead, we needed to first get regulatory approval for our laboratories; therefore, in 2014 and 2015 we had the goal of achieving accreditation.

Firstly, we got the approval through the Community of Madrid, which automatically gave us the accreditation nationwide. This was followed up by the approval on August 9th, 2016 by the Centers of Medicare and Medicaid Services (CMS), the sister agency of the FDA which regulates diagnostic laboratories. This was extremely challenging as there are only a handful of laboratories outside the US that have achieved this, and we are the only one in Spain. Finally, we obtained our ISO 15189 accreditation, which is specific for clinical laboratory testing, and this accreditation gives us regulatory approval to work in around 65 countries.

What about from a technology standpoint?

Up until 2016, we were developing our Telomere Analysis Technology$^{Â®}$ (TAT$^{Â®}$), but hadnâ??t really clearly established clinical applications; meaning, people know about telomeres and their important role in ageing and age-related diseases but didnâ??t have a clear idea of what measuring them could be used for.

We initially had the idea for use in personalized medicines where telomeres length can be viewed as a biological clock and could be used as a biomarker to assess oneâ??s rate of ageing. And while this is true, we have found that for a really big market and wider adoption, providing this information is not enough, as insurance companies and doctors havenâ??t been able to find a way to use this information to formulate a diagnosis, but only really to assess how well a person is ageing as an outcome of their genetics, environment and lifestyle.

If you step back, you can think about lab testing being in two large buckets; black and white tests, such as being pregnant or not, and screening tests, which endeavour to foresee the future â?? at least statistically. For example, cholesterol tests. But even when they indicate high cholesterol, it doesnâ??t automatically equate that you will develop CVD, but that you are definitely at greater risk for doing so.

But in this case, if a patient isnâ??t able to undertake lifestyle changes, then the physician is able to prescribe pharmaceuticals. Unfortunately, we do not yet have medicine for short telomeres, and so this limits the use of the test in screening and for now, the test is an out of pocket cash-pay test used by physicians and their proactive patients as part of programs of preventive or â??conciergeâ?• medicine.

Are people open-minded to the idea of telomere testing?

If you look at the diseases of today, and in the future, they are chronic conditions that are mostly age related. If we can move towards a more preventive medical system â?? as opposed to the current â??reactiveâ?• system, then we have the opportunity to allow individuals to age more healthily and ultimately this will bring down medical costs and thus both insurance companies and public health authorities need to support this.

Nevertheless, the shift from a reactive to pro-active approach is not that easy. There is a psychological barrier to overcome in people, as they want to live without the discipline in eating well,

exercising etc. that is required to age well but still look like the models on fitness magazine covers. Many people prefer not to consider how these lifestyles have long-term health repercussions. Many pharmaceutical companies have begun to move to results-based payments, and this can be extended to individuals be making them responsible for their lifestyle choices by paying higher premiums for those who chose not to take care of their health proactively.

Have you been able to effectively convince insurance companies?

This is something we have tried doing and we continue to try to do. Many of the insurance companies talk a lot about prevention but are yet not willing to really commit the resources to preventive medicine

Moving back to the recent accreditation, what opportunities have they opened up?

As aforementioned, once we got accreditation it was about showing the clinical usage of telomere length measurement with our proprietary assays. We sought and obtained the incredibly competitive grant funding from the E.U.â??s most prestigious program for SMEâ??s â?? Horizon 2020 for â?¬3.1 million for our ONCOCHECK study designed to show the clinical utility of our technology in oncology, going back to our heritage as a spin-off of CNIO. Cancer is an extremely complex disease and each individual case is like a fingerprint; therefore, there is a huge amount of diagnostic testing. Furthermore, cancer is very hard to detect in the early stages, as this is crucial for maximizing an individualâ??s chance for survival.

With more than 7000 peer-reviewed publications indicating telomere length and its role in cancer, we knew it was a good area in which to work. We began the study in January 2017 and it will finish in December 2018. We have focused on two keys areas in diagnostics; prostate cancer, the most common male cancer â?? and lung cancer, another common and deadly cancer and one which is very difficult to detect early.

In prognostic application, we are looking at leukaemia, both CLL and ALL. Leukaemia is relatively easy to detect, though some patients can live for years, while others just months. The challenge is determining the aggressiveness of the disease, and we believe our telomere length assays could contribute to prognosis and help guide treatment decisions.

Finally, we are focusing also on immunotherapies. These treatments are quite costly due to their complicated action of combating cancer while helping the immune system. Many of the medicines used are effective in some patients and ineffective in others. We believe our tests can be one of the tests used to screen patients who will respond to the treatment. This will save the payer a lot of money if we can sift out non-responsive patients from the mix.

What were the results of the studies?

The most important completed study has been in prostate cancer, which entailed over 1,200 patients and has some very strong results have come in. In fact, we have applied for patents based on the outcome of this study

Up until now, the gold standard for prostate patients has been the PSA test, which measures antigens â?? with an elevated level indicating that a patient may have prostate cancer. Just in the US market alone some 20 million men undertake this PSA test every year, with around 1.3 million recording elevated antigen levels. However, this test is only 20 to 30 percent accurate and leads to an enormous number of unnecessary, painful and expensive biopsies, as much as 80 percent turn out to be negative

Our data demonstrates that our TATassay, in conjunction with the PSA data, is actually far more accurate and can contribute to reducing biopsies in prostate cancer by one third or more. This will not only save the payer money but prevent men from undertaking an unneeded invasive procedure that can lead to complications.

How do you ensure your test will be accepted at the same rate as a PSA test?

The two points that will push our technology are patient demand and economics. Firstly, men would rather undergo a simple blood test that can help them avoid an unneeded biopsy, even paying out of pocket if necessary, and doing the biopsy only when the results really justify it. Letting people know they have another option is important.

Secondly, the economic argument, and I will use figures to demonstrate the fact. In the US, there are approximately one million men undergoing a prostate biopsy every year, at a cost of around 2000 USD â?? so in total it costs insurance companies around 2 billion USD annually. 80 percent of these patients do not have prostate cancer, so 1.6 billion USD is really being wasted. With a cost of around 200 USD for our assay, we could eliminate at least 30 percent of biopsies, which would in total save in excess of 400 million USD per year. We are well aware that we are not alone in this field; there is competition in the market but we believe that we can deliver our service at a very attractive price for wide-spread adoption.

We are now submitting patents through AEMPS, the Spanish regulator, which will give us complete EU approval and by 2021 we hope to have US FDA approval

What does the future hold for Life Length?

We will continue to do our personalized tests for telomere length and push to have insurance providers take on board the tests as part of their offering to clients. Additionally, we will provide our services to pharmaceutical, nutraceutical, and vitamin companies for in-vitro and in-vivo testing of their drugs, compounds and supplements. where they are increasingly interested in evaluating the impact on cellular health and ageing that we can uniquely quantify.

We will apply for patents for the tests based on favourable outcomes for our other ongoing studies in leukemia and lung cancer. Again, this will be through AEMPS, then the US FDA, and also, we will be looking to seek approval in other major markets such as China and Japan, through JV partners or licenses.

We will also look towards growing into doing clinical studies for other forms of cancer, and possibly other therapeutic areas related to age. For example, we are currently setting up a partnership with a major US company to do studies in cardiovascular diseases and partnering with a university to do studies related to infertility. We see the future tests to be done through partners, such as pharmaceutical players or be self-funded via the funds being supplied from our commercial sales of other tests.

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